AGENUS INC
Form 10-Q
November 07, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Quarterly Period Ended September 30, 2012

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File No. 000-29089

Agenus Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**06-1562417**
(State of Incorporation)	**(I.R.S. Employer Identification No.)**

3 Forbes Road, Lexington, MA 02421

(Address of Principal Executive Offices, including Zip Code)

(781) 674-4400

(Registrant s Telephone Number, including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

Number of shares outstanding of the issuer s Common Stock as of November 2, 2012: 24,594,167 shares.

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Agenus Inc.

Quarterly Period Ended September 30, 2012

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PART I FINANCIAL INFORMATION

Item 1 ***Financial Statements***

AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2012	December 31, 2011
ASSETS		
Cash and cash equivalents	$ 24,757,867	$ 10,747,951
Accounts receivable	369,059	
Inventories	16,022	20,072
Prepaid expenses	631,843	536,270
Other current assets	15,482	699,786
Total current assets	25,790,273	12,004,079
Plant and equipment, net of accumulated amortization and depreciation of $27,343,321 and $26,081,778 at September 30, 2012 and December 31, 2011, respectively	2,749,772	4,136,699
Goodwill	2,572,203	2,572,203
Other long-term assets	1,111,500	1,094,549
Total assets	$ 32,223,748	$ 19,807,530
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current portion, long-term debt	$ 210,471	$ 197,684
Current portion, deferred revenue	994,800	1,542,395
Accounts payable	467,834	807,928
Accrued liabilities	2,803,799	1,730,290
Other current liabilities	352,184	475,342
Total current liabilities	4,829,088	4,753,639
Convertible notes	35,246,475	32,637,757
Other long-term debt	48,478	88,247
Deferred revenue	3,965,830	2,078,651
Other long-term liabilities	1,290,822	1,080,201
Commitments and contingencies		
Stockholders deficit:		
Preferred stock, par value $0.01 per share; 5,000,000 and 25,000,000 shares authorized at September 30, 2012 and December 31, 2011, respectively:		
Series A convertible preferred stock; 31,620 shares designated, issued, and outstanding at September 30, 2012 and December 31, 2011; liquidation value of $31,817,625 at September 30, 2012	316	316
Series B2 convertible preferred stock; 3,105 shares designated, issued, and outstanding at September 30, 2012 and December 31, 2011	31	31
Common stock, par value $0.01 per share; 70,000,000 and 250,000,000 shares authorized at September 30, 2012 and December 31, 2011, respectively; 24,628,114 and 21,535,037 shares issued at September 30, 2012 and December 31, 2011, respectively	246,282	215,350
Additional paid-in capital	594,920,411	581,392,602
	(324,792)	(324,792)

Treasury stock, at cost; 43,490 shares of common stock at September 30, 2012 and December 31, 2011		
Accumulated deficit	(613,579,317)	(607,694,596)
Noncontrolling interest	5,580,124	5,580,124
Total stockholders deficit	(13,156,945)	(20,830,965)
Total liabilities and stockholders deficit	$ 32,223,748	$ 19,807,530

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Quarters Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue:				
Service revenue	$ 486,833	$	$ 781,591	$
Research and development revenue	381,971	653,681	14,088,925	2,111,994
Total revenues	868,804	653,681	14,870,516	2,111,994
Operating expenses:				
Cost of service revenue	217,186		369,339	
Research and development	2,605,917	2,527,668	8,193,847	8,166,670
General and administrative	2,586,866	2,566,914	8,819,319	8,110,176
Operating loss	(4,541,165)	(4,440,901)	(2,511,989)	(14,164,852)
Other income (expense):				
Non-operating income (expense)	2,880	(298)	110,472	(1,114)
Interest expense, net	(1,191,076)	(1,093,201)	(3,483,204)	(3,089,783)
Net loss	(5,729,361)	(5,534,400)	(5,884,721)	(17,255,749)
Dividends on series A convertible preferred stock	(197,625)	(197,625)	(592,875)	(592,875)
Net loss attributable to common stockholders	$ (5,926,986)	$ (5,732,025)	$ (6,477,596)	$ (17,848,624)
Per common share data, basic and diluted:				
Net loss attributable to common stockholders	(0.24)	(0.28)	(0.28)	(0.92)
Weighted average number of common shares outstanding, basic and diluted	24,529,089	20,225,034	23,275,267	19,352,035

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30,	
	2012	**2011**
Cash flows from operating activities:		
Net loss	$ (5,884,721)	$ (17,255,749)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,487,324	1,696,358
Share-based compensation	3,580,914	1,647,627
Non-cash interest expense	2,708,718	2,350,225
Other	703	14,420
Changes in operating assets and liabilities:		
Accounts receivable	(369,059)	35,000
Inventories	4,050	
Prepaid expenses	(95,573)	(66,847)
Accounts payable	(340,094)	(215,169)
Deferred revenue	1,339,584	(1,141,399)
Accrued liabilities and other current liabilities	1,346,219	1,101,734
Other operating assets and liabilities	511,894	(234,781)
Net cash provided by (used in) operating activities	4,289,959	(12,068,581)
Cash flows from investing activities:		
Proceeds from sale of property and equipment		22,749
Proceeds from maturities of available-for-sale securities		5,000,000
Purchases of available-for-sale securities		(4,998,799)
Purchases of plant and equipment	(101,051)	(54,547)
Net cash used in investing activities	(101,051)	(30,597)
Cash flows from financing activities:		
Net proceeds from sales of equity	10,464,203	7,559,267
Proceeds from employee stock purchases	76,662	82,536
Financing of property and equipment	(26,982)	
Repayment of convertible note	(100,000)	
Payment of series A convertible preferred stock dividends	(592,875)	(592,875)
Net cash provided by financing activities	9,821,008	7,048,928
Net increase (decrease) in cash and cash equivalents	14,009,916	(5,050,250)
Cash and cash equivalents, beginning of period	10,747,951	19,781,976
Cash and cash equivalents, end of period	$ 24,757,867	$ 14,731,726
Non-cash investing and financing activities:		
Convertible Note adjustment to equity for conversion option		$ 5,580,124

Reclassification of derivative liability into equity		$ 755,000
Issuance of senior secured convertible notes as payment in-kind for interest	$ 1,499,981	$ 1,386,817
Note payable for purchase of plant and equipment		$ 171,640

See accompanying notes to unaudited condensed consolidated financial statements.

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AGENUS INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2012

Note A Business, Liquidity and Basis of Presentation

Agenus Inc. (including its subsidiaries, also referred to as Agenus, the Company, we, us, and our) is a biotechnology company developing a commercializing technologies to treat cancers and infectious diseases, primarily based on immunological approaches. Our technology portfolio consists of our Saponin Platform (based on our saponin adjuvant based technologies) and our Heat Shock Protein (HSP) Platform (based on our HSP based technologies). Within our Saponin Platform is QS-21 Stimulon® adjuvant, or QS-21, which is used by our licensees in numerous vaccines under development in trials, some as advanced as Phase 3, for a variety of diseases, including cancer, shingles, malaria, Alzheimer s disease, human immunodeficiency virus, and tuberculosis. Within our HSP Platform we are developing our Recombinant Series and our Prophage Series vaccines. HerpV, a therapeutic vaccine candidate from the Recombinant Series which is administered with QS-21, has been tested in a Phase 1 clinical trial for the treatment of genital herpes and is now entering a Phase 2 trial. In our Prophage Series we have tested product candidates in Phase 3 clinical trials for the treatment of renal cell carcinoma (RCC), the most common type of kidney cancer, and for metastatic melanoma, as well as in Phase 1 and Phase 2 clinical trials in a range of indications. Prophage Series vaccine R-100 is registered for use in Russia for the treatment of RCC in patients at intermediate risk of recurrence as Oncophage® vaccine (vitespen). Product candidates from our Prophage G-Series are currently in Phase 2 clinical trials in glioma, a type of brain cancer. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development activities, market development, and support of our collaborations. Our product candidates require clinical trials and approvals from regulatory agencies, as well as acceptance in the marketplace. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing arrangements with academic and corporate collaborators and licensees and by entering into new collaborations.

We have incurred significant losses since our inception. As of September 30, 2012, we had an accumulated deficit of $613.6 million. Since our inception, we have financed our operations primarily through the sale of equity and convertible notes, and interest income earned on cash, cash equivalents, and short-term investment balances. We believe that, based on our current plans and activities, our working capital resources as of September 30, 2012, along with the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2013. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions, and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The eventual total cost of each clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, and number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because HerpV is entering a Phase 2 trial and the development of our Prophage Series vaccines is subject to further evaluation and uncertainty, we are unable to reliably estimate the cost of completing research and development programs, the timing of bringing such programs to various markets, and, therefore, are unable to determine when, if ever, material cash inflows from operating activities are likely to commence. We will continue to adjust other spending as needed in order to preserve liquidity.

As of September 30, 2012, we had debt outstanding of $39.3 million in principal, including $39.0 million in principal of our 8% senior secured convertible notes due August 2014 (the 2006 Notes). We expect to attempt to raise additional funds in advance of depleting our current funds. We may attempt to raise additional funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities, including, without limitation, in at the market offerings. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) our Oncophage product, our Prophage Series vaccines, and/or HerpV, (2) vaccines containing QS-21 under development by our licensees and/or (3) potentially other product candidates, each of which will require additional capital. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations.

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) for interim financial information and with the

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instructions to Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete annual consolidated financial statements. In the opinion of management, the condensed consolidated financial statements include all normal and recurring adjustments considered necessary for a fair presentation of our financial position and operating results. All significant intercompany transactions and accounts have been eliminated in consolidation. Operating results for the nine months ended September 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012. For further information, refer to our consolidated financial statements and footnotes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission.

Effective June 15, 2012, our certificate of incorporation was amended to decrease the authorized number of shares of our common stock from 250,000,000 shares to 70,000,000 and authorized shares of our preferred stock from 25,000,000 to 5,000,000.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Note B Net Loss Per Share

Basic income and loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our Directors Deferred Compensation Plan, DDCP). Diluted income per common share is calculated by dividing net income attributable to common stockholders by the weighted average number of common shares outstanding (including common shares issuable under our DDCP) plus the dilutive effect of outstanding instruments such as warrants, stock options, nonvested shares, convertible preferred stock, and convertible notes. Because we reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, the following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive:

	September 30,	
	2012	2011
Warrants	3,309,378	3,309,378
Stock options	2,769,311	1,827,458
Nonvested shares	257,415	143,321
Convertible preferred stock	333,333	333,333
Convertible notes		

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Note C Share-Based Compensation

We use the Black-Scholes option pricing model to value options for employees and non-employees as well as options granted to members of our Board of Directors. All stock option grants have a 10-year term and generally vest ratably over a three or four-year period. The non-cash charge to operations for non-employee options with vesting or other performance criteria is affected each reporting period, until the non-employee options are exercised or expire, by changes in the fair value of our common stock. A summary of option activity for the nine months ended September 30, 2012 is presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2011	1,814,161	$ 8.38		
Granted	1,011,750	5.33		
Forfeited	(10,007)	4.65		
Expired	(40,337)	21.95		
Exercised	(6,256)	3.91		
Outstanding at September 30, 2012	2,769,311	$ 7.09	8.0	$ 540,033
Vested or expected to vest at September 30, 2012	2,650,171	$ 7.18	7.9	$ 521,309
Exercisable at September 30, 2012	1,432,068	$ 8.91	6.7	$ 294,654

The weighted average grant-date fair values of options granted during the nine months ended September 30, 2012, and 2011, were $3.94, and $3.52, respectively.

During the nine months ended September 30, 2012, all options were granted with exercise prices equal to the fair market value of the underlying shares of common stock on the grant date. As of September 30, 2012, approximately $4.6 million of total unrecognized compensation cost related to stock options granted to employees and directors is expected to be recognized over a weighted average period of 2.4 years.

As of September 30, 2012, unrecognized expense for options granted to outside advisors for which performance (vesting) has not yet been completed but the exercise price of the option is known is approximately $46,000. Such amount is subject to change each reporting period based upon changes in the fair value of our common stock, expected volatility, and the risk-free interest rate, until the outside advisor completes his or her performance under the option agreement.

Certain employees and consultants have been granted nonvested stock. The fair value of nonvested stock is calculated based on the closing sale price of the Company s common stock on the date of grant.

A summary of nonvested stock activity for the nine months ended September 30, 2012 is presented below:

	Nonvested Shares	Weighted Average

		Grant Date Fair Value
Outstanding at December 31, 2011	135,791	$ 5.85
Granted	644,557	4.42
Vested	(515,763)	4.30
Forfeited	(7,170)	6.23
Outstanding at September 30, 2012	257,415	5.36

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As of September 30, 2012, there was approximately $1.2 million of unrecognized share-based compensation expense related to these nonvested shares. This cost is expected to be recognized over a weighted average period of 2.5 years. The total intrinsic value of shares vested during the nine months ended September 30, 2012 was approximately $2.1 million.

We issue new shares upon option exercises, purchases under the 2009 Employee Stock Purchase Plan (the 2009 ESPP), vesting of nonvested stock, under the DDCP, and in lieu of approximately 32% of the base salary of our Chief Executive Officer (CEO). During the nine months ended September 30, 2012, approximately 29,000 shares were issued under the 2009 ESPP, and approximately 516,000 shares were issued as a result of the vesting of nonvested stock. In addition, during the nine months ended September 30, 2012, approximately 33,000 shares were issued under the DDCP, approximately 30,000 shares were issued to our CEO in lieu of cash salary, and approximately 6,000 shares were issued upon exercise of options.

The impact on our results of operations from the granting of stock options and nonvested shares and issuing shares for services was as follows (in thousands):

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Research and development	$ 255	$ 126	$ 901	$ 395
General and administrative	558	317	2,680	1,253
Total share-based compensation expense	$ 813	$ 443	$ 3,581	$ 1,648

Note D License Agreements

In March 2012, we entered into a First Right to Negotiate and Amendment Agreement with GlaxoSmithKline (GSK) whereby we granted GSK the first right to negotiate for the purchase of Agenus or certain of our assets and further amended certain existing agreements to clarify certain provisions and grant GSK an additional license and rights thereunder. The first right to negotiate will expire after five years. Under the terms of the agreement, GSK paid us a nonrefundable payment of $9.0 million, of which $2.5 million is creditable against future manufacturing technology transfer royalty payments. The agreement provides GSK with an additional license to an undisclosed indication and also provides for additional royalty payments for this indication upon commercialization of a vaccine product. Also during March 2012, we received $6.25 million through an amended license of non-core technologies with an existing licensee. This amendment converted the license grant from non-exclusive to exclusive and enabled the licensee to buy-out the current royalty stream structure. As we have no future service obligation under these agreements, we recognized $12.8 million in revenue related to these amendments during the nine months ended September 30, 2012 and included $2.5 million in deferred revenue in our condensed consolidated financial statements.

Note E Other Current Liabilities

Other current liabilities consist of the following as of September 30, 2012 and December 31, 2011 (in thousands)

	September 30, 2012	December 31, 2011
Deferred rent expense	$	$ 405
Value of liability classified option grants	216	70
Other	136	
	$ 352	$ 475

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Note F Equity

During the quarter ended March 31, 2012, we terminated our existing At Market Issuance Sales Agreement with MLV & Co. LLC and Wm Smith & Co., as sales agents (the Old ATM Program), and entered into a new At Market Issuance Sales Agreement with MLV & Co. LLC, as sales agent, under which we may sell from time to time up to 5,000,000 shares of our common stock (the New ATM Program).

During the nine months ended September 30, 2012, we sold an aggregate of approximately 952,000 shares of our common stock in at the market offerings under the Old ATM Program and received net proceeds of approximately $2.8 million after deducting offering costs of approximately $87,000 and an aggregate of approximately 1,518,000 shares of our common stock in at the market offerings under the New ATM Program and received net proceeds of approximately $7.7 million after deducting offering costs of approximately $244,000. These offerings were made under effective shelf registration statements and proceeds from the offerings will be used for general corporate purposes.

Note G Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update No. 2011-05, Comprehensive Income (ASU 2011-05) which increases the prominence of other comprehensive income in financial statements. Under this standard, the components of net income and other comprehensive income must be presented in either one or two consecutive financial statements. The standard eliminates the option to present other comprehensive income in the statement of changes in equity. ASU 2011-05 was effective for fiscal years beginning after December 15, 2011 and interim and annual periods thereafter. The standard should be applied retrospectively and early adoption is permitted. In December 2011, the FASB decided to defer the effective date of those changes in ASU 2011-05 that relate only to the presentation of reclassification adjustments in the statement of income by issuing ASU 2011-12, Comprehensive Income. Adoption of this standard did not have a material effect on our financial statements.

In September 2011, the FASB amended the guidance on the annual testing of goodwill for impairment. This amended guidance permits companies to assess qualitative factors to determine whether to perform the two-step goodwill impairment test. This amendment is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. We do not anticipate any material impact of this guidance on our consolidated financial statements.

In July 2012, the FASB issued Accounting Standard Update No. 2012-02, Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02). ASU 2012-02 simplifies the guidance for testing the impairment of indefinite-lived intangible assets other than goodwill. The guidance allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. An entity electing to perform a qualitative assessment is no longer required to calculate the fair value of an indefinite-lived intangible asset unless the entity determines, based on a qualitative assessment, that it is more likely than not that the asset is impaired. This guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. We do not anticipate any material impact of this guidance on our consolidated financial statements.

Note H Fair Value Measurements

The estimated fair values of all of our financial instruments, excluding long-term debt, approximate their carrying amounts in the consolidated balance sheets. The fair value of our long-term debt was derived by evaluating the nature and terms of each note and considering the prevailing economic and market conditions at the balance sheet date.

As of September 30, 2012 and December 31, 2011, $39.0 million and $37.5 million, respectively, in principal of the 2006 Notes were outstanding. The fair value of the debt portion of the 2006 Notes exclusive of the conversion option at September 30, 2012, and December 31, 2011, was $32.1 million and $30.8 million, respectively, based on a present value methodology. The fair value of the embedded conversion option at September 30, 2012 and December 31, 2011, was $2.0 million and $988,000, respectively.

Note I Subsequent Events

We have evaluated subsequent events and did not identify any events that required disclosure or recognition.

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Item 2. ***Management s Discussion and Analysis of Financial Condition and Results of Operations***

Overview

Our current research and development activities are focused on developing technologies and product candidates to treat cancers and infectious diseases. Our core technology portfolio consists of our Saponin Platform (based on our saponin adjuvant based technologies) and our Heat Shock Protein (HSP) Platform (based on our HSP based technologies). Some of our key candidates from these technology platforms are QS-21 Stimulon® adjuvant (QS-21), HerpV, and the Prophage Series vaccines.

QS-21 is an adjuvant, or a substance added to a vaccine or other immunotherapy that is intended to enhance immune response. The key licensees of QS-21 are GlaxoSmithKline (GSK) and JANSSEN Alzheimer Immunotherapy (JANSSEN AI). There are approximately 17 vaccines containing QS-21 in clinical development by our licensees, including a total of four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are anticipated to be launched in the 2014 timeframe, and we are generally entitled to royalties for at least 10 years post-launch, with some exceptions.

HerpV is derived from our HSP Platform technologies, and is a recombinant, synthetic, non-patient specific therapeutic vaccine candidate administered with QS-21 for the treatment of genital herpes. It has completed Phase 1 testing, where it was shown to elicit both CD4 and CD8 positive T cell responses a first of its kind finding in genital herpes treatment. Because the product contains multiple antigens derived from the herpes simplex 2 virus (HSV-2), it may be applicable to a broader patient population and may have potential in managing outbreaks and disease transmission. We consider this to be a platform technology, since we could potentially create therapeutic vaccines for various infectious diseases with the integration of heat shock proteins with antigenic peptides. We initiated a Phase 2 trial in October 2012.

The Prophage Series vaccines are a patient specific application of our HSP Platform. The Prophage Series vaccine R-100 is referred to as Oncophage® vaccine (vitespen) and is approved in Russia for the treatment of renal cell carcinoma (RCC , or kidney cancer) in patients at intermediate risk of recurrence. In December 2011, we granted NewVac LLC (a subsidiary of ChemRar Ventures LLC) an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. A Phase 2 trial testing the Prophage Series vaccine candidate G-100 in newly diagnosed glioma has been fully enrolled and patient follow up is underway. Separately, a Phase 2 trial with G-200 in recurrent glioma has been completed and final data are in the process of being prepared for publication in a peer reviewed medical journal. The G-100 and G-200 studies are solely based in the United States.

In addition to our internal development efforts, we continue to pursue partnering opportunities. We are seeking partners for select products in our portfolio, which include the Prophage G-Series vaccines, G-100 and G-200, QS-21, and HerpV. We are also exploring in-licensing, acquisitions and sponsored research opportunities. Our business activities have included product research and development, intellectual property prosecution, manufacturing, regulatory and clinical affairs, corporate finance and development, market development, business development, and support of our collaborations. Research and development expenses for the nine months ended September 30, 2012 and for the years ended December 31, 2011, 2010, and 2009, were $8.2 million, $11.0 million, $12.9 million, and $16.9 million, respectively. We have incurred significant losses since our inception. As of September 30, 2012, we had an accumulated deficit of $613.6 million.

We have financed our operations primarily through the sale of equity and convertible notes. We believe that, based on our current plans and activities, our working capital resources at September 30, 2012, along with the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2013 based on our annual rate of net cash burn (defined as cash used in operating activities less one-time upfront payments, plus capital expenditures and dividend payments) of $13-16 million during 2012. We expect to attempt to raise additional funds in advance of depleting our funds. We may attempt to raise additional funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities, including, without limitation, in at the market offerings. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) our Oncophage product, our other Prophage Series vaccines, and/or HerpV, (2) vaccines containing QS-21 under development by our licensees, and/or (3) potentially other product candidates, each of which will require additional capital.

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Forward-Looking Statements

This Quarterly Report on Form 10-Q and other written and oral statements the Company makes from time to time contain certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the Exchange Act). You can identify these forward-looking statements by the fact they use words such as could, expect, anticipate, estimate, target, may, project, guidance, intend, plan, believe, will, potential, opportunity, future and other words and te and expression in connection with any discussion of future operating or financial performance. You can also identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. These statements are likely to relate to, among other things, our business strategy, our research and development, our product development efforts, our ability to commercialize our product candidates, the activities of our licensees, our prospects for initiating partnerships or collaborations, the timing of the introduction of products, the effect of new accounting pronouncements, uncertainty regarding our future operating results and our profitability, anticipated sources of funds as well as our plans, objectives, expectations, and intentions.

Although the Company believes it has been prudent in its plans and assumptions, no assurance can be given that any goal or plan set forth in forward-looking statements can be achieved and readers are cautioned not to place undue reliance on such statements, which speak only as of the date made. The Company undertakes no obligation to release publicly any revisions to forward-looking statements as a result of new information, future events, or otherwise.

We have included more detailed descriptions of these risks and uncertainties and other risks and uncertainties applicable to our business that the Company believes could cause actual results to differ materially from any forward-looking statements in Part II-Item 1A Risk Factors of this Quarterly Report on Form 10-Q. We encourage you to read those descriptions carefully. We caution investors not to place significant reliance on forward-looking statements contained in this document; such statements need to be evaluated in light of all the information contained in this document. Furthermore, the statements speak only as of the date of this document, and we undertake no obligation to update or revise these statements.

Historical Results of Operations

Quarter Ended September 30, 2012 Compared to the Quarter Ended September 30, 2011

Revenue: We generated revenue of $869,000 and $654,000 during the quarters ended September 30, 2012 and 2011, respectively. Revenue includes license fees, royalties earned, and in 2012, service revenue. During the quarters ended September 30, 2012 and 2011, we recorded revenue of $382,000 and $385,000, respectively, from the amortization of deferred revenue.

Research and Development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, administrative costs, and services provided by clinical research organizations. Research and development expenses increased 3% to $2.6 million for the quarter ended September 30, 2012 from $2.5 million for the quarter ended September 30, 2011. The change includes increased expenses related to our HerpV program and non-cash share-based compensation expense and is partially offset by decreased expenses related to our general cost-containment efforts and the status of our other products under development.

General and Administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses held steady at $2.6 million for the quarter ended September 30, 2012 from the quarter ended September 30, 2011.

Interest Expense, net: Interest expense, net, increased to $1.2 million for the quarter ended September 30, 2012 from $1.1 million for the quarter ended September 30, 2011 due to the increased principal amount outstanding of our 8% senior secured convertible notes due August 2014 (the 2006 Notes). The principal of our 2006 Notes increased due to the payment of interest with additional notes.

Nine Months Ended September 30, 2012 Compared to the Nine Months Ended September 30, 2011

Revenue: We generated revenue of $14.9 million and $2.1 million during the nine months ended September 30, 2012 and 2011, respectively. Revenue includes license fees, royalties earned, and in 2012, service revenue. For the nine months ended September 30, 2012, we recognized

revenue of $6.5 million through an expanded license agreement with GSK, which provided GSK with an additional license to an undisclosed indication, and $6.25 million through a license of non-core technologies with an existing licensee that resulted in a buy-out of the current royalty stream related to the license.

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During each of the nine months ended September 30, 2012 and 2011, we recorded revenue of $1.2 million from the amortization of deferred revenue. Our revenue for the nine months ended September 30, 2012 primarily resulted from one-time payments received under amended license agreements and therefore is not indicative of future results.

Research and Development: Research and development expenses include the costs associated with our internal research and development activities, including compensation and benefits, occupancy costs, clinical manufacturing costs, administrative costs, and services provided by clinical research organizations. Research and development expenses held steady at $8.2 million for the nine months ended September 30, 2012 as compared to the same period in the prior year. Increased expenses related to our HerpV program and non-cash share-based compensation expense were offset by decreased expenses related to our general cost-containment efforts and the status of our other products under development.

General and Administrative: General and administrative expenses consist primarily of personnel costs, facility expenses, and professional fees. General and administrative expenses increased 9% to $8.8 million for the nine months ended September 30, 2012 from $8.1 million for the nine months ended September 30, 2011. Our non-cash share-based compensation expense increased $1.5 million for the nine months ended September 30, 2012 over the same period in 2011. This increase was partially offset by decreased expenses related to our general cost-containment efforts.

Interest Expense, net: Interest expense, net, increased to $3.5 million for the nine months ended September 30, 2012 from $3.1 million for the nine months ended September 30, 2011 due to the increased principal amount outstanding of our 2006 Notes. The principal of our 2006 Notes increased due to the payment of interest with additional notes.

Research and Development Programs

Prior to 2002, we did not track costs on a per project basis, and therefore have estimated the allocation of our total research and development costs to our largest research and development programs for that time period. During the nine months ended September 30, 2012, these research and development programs consisted largely of our Prophage Series vaccines as indicated in the following table (in thousands).

Research and Development Program	Product	Nine Months Ended September 30, 2012	Year Ended December 31, 2011	2010	2009	Prior to 2009	Total
Heat Shock Proteins for Cancer	Prophage Series Vaccines	$ 4,320	$ 10,182	$ 10,960	$ 15,309	$ 255,582	$ 296,353
Heat Shock Proteins for Infectious Diseases	HerpV	3,810	734	644	262	17,448	22,898
Vaccine adjuvant *	QS-21	64	94	1,185	1,071	10,148	12,562
Other Research and Development Programs			13	89	261	33,177	33,540
Total Research and Development Expenses		$ 8,194	$ 11,023	$ 12,878	$ 16,903	$ 316,355	$ 365,353

* Prior to 2000, costs were incurred by Aquila Biopharmaceuticals, Inc., a company we acquired in November 2000.

Research and development program costs include compensation and other direct costs plus an allocation of indirect costs, based on certain assumptions and our review of the status of each program. Our product candidates are in various stages of development and significant additional expenditures will be required if we start new trials, encounter delays in our programs, apply for regulatory approvals, continue development of our technologies, expand our operations, and/or bring our product candidates to market. The eventual total cost of each clinical trial is dependent on a number of factors such as trial design, length of the trial, number of clinical sites, and number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive, and uncertain. Because HerpV is now

entering a Phase 2 trial and the further development of our Prophage Series vaccines is subject to evaluation and uncertainty, we are unable to reliably estimate the cost of completing our research and development programs, the timing of bringing such programs to various markets, and, therefore, when, if ever, material cash inflows are likely to commence. Programs involving QS-21, other than our HerpV program, depend on our collaborative partners or licensees successfully completing clinical trials, successfully manufacturing QS-21 to meet demand, obtaining regulatory approvals and successfully commercializing product candidates containing QS-21.

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Product Development Portfolio

QS-21

QS-21 Stimulon® adjuvant, from our Saponin Platform, is an adjuvant, or a substance added to a vaccine or other immunotherapy that is intended to enhance immune response. The key licensees of QS-21 are GSK and JANSSEN AI. There are approximately 17 vaccines containing QS-21 in clinical development by our licensees, including a total of four in Phase 3 testing for malaria, melanoma, non-small cell lung cancer and shingles. The first products containing QS-21 are anticipated to be launched in the 2014 timeframe, and we are generally entitled to royalties for at least 10 years post-launch, with some exceptions. However, there is no guarantee that we will be able to collect royalties in the future. The pipeline of product candidates containing QS-21 is extraordinarily diverse, encompassing prophylactic as well as therapeutic vaccines for infectious diseases, multiple cancer types, and Alzheimer s disease. We do not incur clinical development costs for these licensed products.

HerpV

In October 2005, we initiated a multicenter Phase 1 clinical trial of HerpV in HSV-2 (genital herpes). In this four-arm, phase 1 study, 35 HSV-2 seropositive patients received HerpV with QS-21, HerpV alone, QS-21 alone, or placebo. The vaccine was well tolerated, with injection site pain as the most common reported adverse event. This study is the first to demonstrate that HSPs complexed to viral antigens induce an antigen-specific T cell response in humans. The results from this study were published in the peer-reviewed journal *Vaccine* in September 2011. We have advanced HerpV into a Phase 2 study during the fourth quarter of 2012 that will measure the effect of vaccination on viral shedding in individuals infected with HSV-2. Experts in HSV-2 clinical research believe that a reduction in viral shedding could translate into clinical benefit.

Prophage Series Vaccines

We started enrolling patients in our first clinical trial studying a Prophage Series vaccine at Memorial Sloan-Kettering Cancer Center in New York, New York in November 1997. To date, nearly 900 cancer patients have been treated with our vaccine in clinical trials. Because Prophage Series vaccines are novel therapeutic vaccines that are patient-specific, meaning derived from the patient s own tumor, they are experiencing a long development process and high development costs, either of which could delay or prevent our commercialization efforts.

We believe that the collective results from our clinical trials to date with product candidates from the Prophage Series indicate a favorable safety profile and signals of efficacy in multiple cancer types. We also believe that available results from clinical trials suggest that treatment with the Prophage Series vaccines can generate immunological and anti-tumor responses. The Prophage Series vaccine R-100 is referred to as Oncophage® vaccine (vitespen) and is approved in Russia for the treatment of RCC in patients at intermediate risk of recurrence. A Phase 2 trial testing the Prophage Series vaccine candidate G-100 in newly diagnosed giloma has been fully enrolled and patient follow up is underway. Separately, a Phase 2 trial with G-200 in recurrent glioma has been completed and final data are in the process of being prepared for publication in a peer reviewed medical journal. The G-100 and G-200 studies are solely based in the United States.

Liquidity and Capital Resources

We have incurred annual operating losses since inception, and we had an accumulated deficit of $613.6 million as of September 30, 2012. We expect to incur significant losses over the next several years as we continue clinical trials, apply for regulatory approvals, prepare for commercialization, and continue development of our technologies. We have financed our operations primarily through the sale of equity and convertible notes, and interest income earned on cash, cash equivalents, and short-term investment balances. From our inception through September 30, 2012, we have raised aggregate net proceeds of $524.9 million through the sale of common and preferred stock, the exercise of stock options and warrants, proceeds from our employee stock purchase plan, and the issuance of convertible notes. During the quarter ended March 31, 2012, we received $9.0 million from GSK for a First Right to Negotiate and an expanded license agreement and $6.25 million through a license of non-core technologies with an existing licensee. The expanded license agreement provides GSK with an additional license to an undisclosed indication and also provides for additional royalty payments for this indication upon commercialization of a vaccine product. The license of non-core technologies converted a license grant from non-exclusive to exclusive and enabled the licensee to buy-out the current royalty stream structure. We also terminated our prior At the Market Issuance Sales Agreement and entered into a new At the Market Issuance Sales Agreement with MLV & Co. LLC (the Sales Agent) under which we may sell an aggregate of up to 5,000,000 shares of our common stock from time to time through the Sales Agent. As of September 30, 2012, we had debt outstanding of $39.3 million in principal, including $39.0 million in principal of our 2006 Notes maturing August 31, 2014.

Our cash and cash equivalents at September 30, 2012 were $24.8 million, an increase of $14.0 million from December 31, 2011. This increase primarily resulted from one-time payments received under amended license agreements

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of $15.3 million as well as net proceeds of $10.5 million received from at the market offerings and therefore is not indicative of our future financial condition. However, we believe that, based on our current plans and activities, our cash balance, along with the estimated additional proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2013 based on our estimated net cash burn (defined as cash used in operating activities less one-time upfront payments, plus capital expenditures and dividend payments) of $13-16 million during 2012. We continue to monitor the likelihood of success of our key initiatives and are prepared to discontinue funding of such activities if they do not prove to be feasible, restrict capital expenditures and/or reduce the scale of our operations.

We expect to attempt to raise additional funds in advance of depleting our current funds. In order to fund our operations through 2013 and beyond, we will need to contain costs and raise additional funds. We may attempt to raise additional funds by: (1) out-licensing technologies or products to one or more third parties, (2) renegotiating third party agreements, (3) selling assets, (4) securing additional debt financing and/or (5) selling equity securities, including, without limitation, in at the market offerings. Our ability to successfully enter into any such arrangements is uncertain, and if funds are not available, or not available on terms acceptable to us, we may be required to revise our planned clinical trials, other development activities, capital expenditures, and/or the scale of our operations. While we expect to attempt to raise additional funds in advance of depleting our current funds, we may not be able to raise funds or raise amounts sufficient to meet the long-term needs of the business. Satisfying long-term liquidity needs may require the successful commercialization and/or one or more partnering arrangements for (1) our Oncophage product, other Prophage Series vaccines, and/or HerpV, (2) vaccines containing QS-21 under development by our licensees, and/or (3) potentially other product candidates, each of which will require additional capital. We hope to earn royalties from our QS-21 product in the 2014 timeframe. Please see the risks highlighted under Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

Our future cash requirements include, but are not limited to, supporting clinical trial and regulatory efforts and continuing our other research and development programs. Since inception, we have entered into various agreements with institutions and clinical research organizations to conduct and monitor our clinical studies. Under these agreements, subject to the enrollment of patients and performance by the applicable institution of certain services, we have estimated our payments to be $52.1 million over the term of the studies. Through September 30, 2012, we have expensed $47.5 million as research and development expenses and $47.3 million has been paid related to these clinical studies. The timing of expense recognition and future payments related to these agreements is subject to the enrollment of patients and performance by the applicable institution of certain services.

We have also entered into sponsored research agreements related to our product candidates that required payments of $6.5 million, all of which has been paid as of September 30, 2012. We plan to enter into additional sponsored research agreements, and we anticipate significant additional expenditures will be required to advance our clinical trials, apply for regulatory approvals, continue development of our technologies, and bring our product candidates to market. Part of our strategy is to develop and commercialize some of our product candidates by continuing our existing collaborative arrangements with academic and collaborative partners and licensees and by entering into new collaborations. As a result of our collaborative agreements, we will not completely control the efforts to attempt to bring those product candidates to market. We have various agreements, for example, with collaborative partners and/or licensees, which allow the use of our QS-21 adjuvant in numerous vaccines. These agreements grant exclusive worldwide rights in some fields of use and co-exclusive or non-exclusive rights in others. These agreements generally provide us with rights to manufacture and supply QS-21 to the collaborative partner or licensee and also call for royalties to be paid to us on future sales of licensed vaccines that include QS-21, which may or may not be achieved. Significant investment in manufacturing capacity could be required if we were to retain our manufacturing and supply rights.

Net cash provided by operating activities for the nine months ended September 30, 2012 was $4.3 million while cash used in operating activities for the nine months ended September 30, 2011 was $12.1 million. This increase in cash provided by operating activities for the period ended September 30, 2012 primarily resulted from one-time payments received under amended license agreements and therefore is not indicative of future results. During the nine months ended September 30, 2012, we recognized revenue of $12.8 million related to expanded license agreements. We continue to support and develop our QS-21 partnering collaborations, with the goal of earning royalties from this product in the 2014 timeframe. Our future ability to generate cash from operations will depend on achieving regulatory approval of our product candidates, and market acceptance of Oncophage and our product candidates, achieving benchmarks as defined in existing collaborative agreements, and our ability to enter into new collaborations. Please see the risks highlighted under Part II-Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

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Recent Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standard Update No. 2011-05, Comprehensive Income (ASU 2011-05) which increases the prominence of other comprehensive income in financial statements. Under this standard, the components of net income and other comprehensive income must be presented in either one or two consecutive financial statements. The standard eliminates the option to present other comprehensive income in the statement of changes in equity. ASU 2011-05 is effective for fiscal years beginning after December 15, 2011 and interim and annual periods thereafter. The standard should be applied retrospectively and early adoption is permitted. In December 2011, the FASB decided to defer the effective date of those changes in ASU 2011-05 that relate only to the presentation of reclassification adjustments in the statement of income by issuing ASU 2011-12, Comprehensive Income. Adoption of this standard did not have a material effect on our financial statements.

In September 2011, the FASB amended the guidance on the annual testing of goodwill for impairment. This amended guidance permits companies to assess qualitative factors to determine whether to perform the two-step goodwill impairment test. This amendment is effective for fiscal years beginning after December 15, 2011 with early adoption permitted. We do not anticipate any material impact of this guidance on our consolidated financial statements.

In July 2012, the FASB issued Accounting Standard Update No. 2012-02, Intangibles Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment (ASU 2012-02). ASU 2012-02 simplifies the guidance for testing the impairment of indefinite-lived intangible assets other than goodwill. The guidance allows an entity the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. An entity electing to perform a qualitative assessment is no longer required to calculate the fair value of an indefinite-lived intangible asset unless the entity determines, based on a qualitative assessment, that it is more likely than not that the asset is impaired. This guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. We do not anticipate any material impact of this guidance on our consolidated financial statements.

Item 3. ***Quantitative and Qualitative Disclosures About Market Risk***

In the normal course of business, we are exposed to fluctuations in interest rates as we seek debt financing and invest excess cash. We are also exposed to foreign currency exchange rate fluctuation risk related to our transactions denominated in foreign currencies. We do not currently employ specific strategies, such as the use of derivative instruments or hedging, to manage these exposures. Our currency exposures vary, but are primarily concentrated in the Euro. There has been no material change with respect to our interest rate and foreign currency exposures or our approach toward those exposures, as described in our Annual Report on Form 10-K for the year ended December 31, 2011. However, we are exploring possible commercialization of Oncophage outside of the U.S., which could result in increased foreign currency exposure.

We had cash and cash equivalents at September 30, 2012 of $24.8 million, which are exposed to the impact of interest rate changes, and our interest income fluctuates as interest rates change. Due to the short-term nature of our investments in money market funds, the carrying value approximates the fair value of these investments at September 30, 2012, however, we are subject to investment risk.

We invest our cash, and cash equivalents, and short-term investments in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain liquidity to meet operating needs, and maximize yields. We review our investment policy annually and amend it as deemed necessary. Currently, our investment policy prohibits investing in any structured investment vehicles and asset-backed commercial paper. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer, or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not invest in derivative financial instruments. Accordingly, we do not believe that there is currently any material market risk exposure with respect to derivatives or other financial instruments that would require disclosure under this item.

Item 4. ***Controls and Procedures***

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and Rule 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our Chief Executive Officer and our Principal Financial Officer concluded that, as of the end of the period

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covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective and were designed to ensure that information we are required to disclose in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms. It should be noted that any system of controls is designed to provide reasonable, but not absolute, assurances that the system will achieve its stated goals under all reasonably foreseeable circumstances. Our Chief Executive Officer and Principal Financial Officer have each concluded that our disclosure controls and procedures as of the end of the period covered by this report are effective at a level that provides such reasonable assurances.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 30, 2012, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. ***Legal Proceedings***

We are not currently a party to any material pending legal proceedings, other than ordinary routine litigation incidental to our business. We may currently be a party, or may become a party, to legal proceedings, claims and investigations that arise in the ordinary course of business such as, but not limited to, patent, employment, commercial and environmental matters. While we currently believe that the ultimate outcome of any of these proceedings will not have a material adverse effect on our financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

Item 1A. ***Risk Factors***

Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. We cannot assure investors that our assumptions and expectations will prove to have been correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. Please see the Management s Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Statements section of this Quarterly Report on Form 10-Q. Factors that could cause or contribute to such differences include those factors discussed below.

Risks Related to our Business

If we incur operating losses for longer than we expect, or we are not able to raise additional capital, we may be unable to continue our operations, or we may become insolvent.

Our net losses for the for the nine months ended September 30, 2012 and the years ended December 31, 2011, 2010, and 2009, were $5.9 million, $23.3 million, $21.9 million, and $30.3 million, respectively. During the nine months ended September 30, 2012, we generated a significantly smaller net loss due primarily to revenue generated from amendments of certain license agreements during the first quarter. Therefore, our smaller net loss for the nine months ended September 30, 2012 is not indicative of future results. We expect to incur additional losses for the remainder of fiscal 2012 and over the next several years as we continue research and clinical development of our technologies, apply for regulatory approvals, and pursue partnering opportunities, commercialization, and related activities. Furthermore, our ability to generate cash from operations is dependent on the success of our licensees and collaborative partners, as well as the likelihood and timing of new strategic licensing and partnering relationships and/or successful development and commercialization of vaccines containing QS-21, our Prophage Series vaccines and our other product candidates. If we incur operating losses for longer than we expect and/or we are unable to raise additional capital, we may become insolvent and be unable to continue our operations. From our inception through September 30, 2012, we have incurred net losses totaling $613.6 million.

On September 30, 2012, we had $24.8 million in cash and cash equivalents. We believe that, based on our current plans and activities, our working capital resources at September 30, 2012, along with the estimated proceeds from our license, supply, and collaborative agreements, will be sufficient to satisfy our liquidity requirements through the fourth quarter of 2013 based on our estimated rate of net cash burn (defined as cash used in operating activities less one-time upfront payments, plus capital expenditures and dividend payments) of $13-16 million during 2012. We expect to attempt to raise additional funds in advance of depleting our funds although additional funding may not be available on favorable terms, or at all. For the nine months ended September 30, 2012, our average monthly cash provided by operating activities was $477,000. This average monthly cash provided by operating activities primarily resulted from one-time payments received under amended license agreements and therefore our net cash provided by operations for the nine months ended September 30, 2012 is not indicative of future results. We do not anticipate significant capital expenditures during the remainder of 2012.

We have financed our operations primarily through the sale of equity and convertible notes. In order to finance future operations, we will be required to raise additional funds in the capital markets, through arrangements with collaborative partners, or from other sources. Additional financing may not be available on favorable terms, or at all. If we are unable to raise additional funds when we need them we may not be able to continue some or all of our operations, or we may become insolvent. We also may be forced to license or sell technologies to others under agreements that allocate to third parties substantial portions of the potential value of these technologies.

The weakness of the United States economy and the global economy may have a material adverse effect on our liquidity and financial condition, particularly if our ability to raise additional funds is impaired. This weakness could be worsened by the fiscal cliff tax increases and spending cuts that will go into effect automatically January 1, 2013 in absence of prior congressional action. The ability of potential patients and/or health care payers to pay for our products could also be adversely impacted, thereby limiting our potential revenue. In addition, any negative impacts from any further deterioration in the credit markets and related financial crisis on our collaborative partners could limit potential revenue from

our product candidates.

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We have significant debt, and we may not be able to make interest or principal payments when due.

As of September 30, 2012, we had debt outstanding of $39.3 million in principal, including $39.0 million in principal of our 8% senior secured convertible notes due August 2014 (the 2006 Notes).

Our ability to satisfy our obligations will depend upon our future performance, which is subject to many factors, including the factors identified in this Risk Factors section and other factors beyond our control. If we are not able to generate sufficient cash flow from operations in the future to service our indebtedness, we may be required, among other things, to:

- seek additional financing in the debt or equity markets;
- refinance or restructure all or a portion of our indebtedness;
- sell, out-license, or otherwise dispose of assets; and/or
- reduce or delay planned expenditures on research and development and/or commercialization activities.

Such measures might not be sufficient to enable us to make principal and interest payments. In addition, any such financing, refinancing, or sale of assets might not be available on economically favorable terms, if at all.

Other than for the nine months ended September 30, 2012, we have had negative cash flows from operations. The net cash provided by operations of $4.3 million for the nine month period ended September 30, 2012, primarily resulted from one-time payments received under amended license agreements and therefore our net cash provided by operations for the nine months ended September 30, 2012 is not indicative of future results. For the years ended December 31, 2011, 2010, and 2009, net cash used in operating activities was $16.2 million, $14.8 million, and $24.2 million, respectively.

Our 2006 Notes contain restrictive covenants and are convertible into an equity interest in one of our subsidiaries that holds important rights to certain of our QS-21 Stimulon® adjuvant and HerpV technology.

Our 2006 Notes, due August 2014, are secured by the equity of our wholly-owned subsidiary that holds the QS-21 and HerpV technologies. At the option of the holders, our 2006 Notes can be converted in whole or in part into an equity interest in this subsidiary, subject to our ability to preempt the conversion by redeeming the 2006 Notes to be so converted at a price equal to the conversion amount of such notes plus an amount that, when taken together with any cash interest payments previously made with respect to such 2006 Notes, would generate a 30% annual internal rate of return to the holders. If converted into an equity interest of this subsidiary, the ownership interest in the subsidiary will be determined by multiplying (x) the quotient of the conversion amount divided by $25.0 million, by (y) 30%. In addition, our 2006 Notes grant holders a right of first refusal in any future equity issuance in this subsidiary so that holders of our 2006 Notes may purchase up to 50% of any newly issued equity in this subsidiary. Our 2006 Notes contain a number of restrictions and covenants, including, but not limited to, restrictions and covenants that limit our ability, and the ability of our subsidiary mentioned above, to:

- incur certain additional indebtedness;
- make certain investments;
- enter into certain affiliated party transactions;

create certain liens;

consolidate, merge, sell or otherwise dispose of our assets; and/or

change our line of business.

If the holders elect not to convert into the subsidiary, then at the maturity of the 2006 Notes, we may elect to repay the then outstanding balance in cash or in common stock, subject to certain limitations. If we elect to repay the notes in common stock, we are limited to the number of shares we can issue, whereby the note holders cannot beneficially own in excess of 9.99% of our outstanding common stock at any given time. See We have significant debt, and we may not be able to make interest or principal payments when due. At September 30, 2012, the outstanding principal balance of the 2006 Notes was $39.0 million.

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We may not receive anticipated QS-21 revenues from our licensees.

With the exception of our HerpV program we currently rely upon and expect to continue to rely upon third party licensees, particularly GSK and JANSSEN AI, to develop, test, market and manufacture vaccines that utilize our QS-21 adjuvant. We expect that we will rely on similar relationships if we develop new adjuvants in our Saponin Platform.

In return for rights to use QS-21, our licensees have generally agreed to pay us license fees, supply payments, milestone payments and royalties on product sales for a minimum of 10 years after commercial launch, with some exceptions. As each licensee controls its own product development process, we cannot predict our licensees requirements for QS-21 in the future or to what extent, if any, they will develop vaccines that use QS-21 as an adjuvant. Our licensees may initiate or cease programs containing QS-21 at any time. In the event that our licensees develop vaccines using QS-21, there is no guarantee that these products will obtain regulatory approval or, if so approved, will generate significant royalties, if any, or that we will be able to collect royalties in the future.

In addition, where we had previously supplied GSK and JANSSEN AI with all their requirements of QS-21, we have amended our agreements so that they are permitted to manufacture their own QS-21. We are unable to predict what amount of QS-21, if any, will be purchased from us by other licensees or collaborators in the future. Any such inability to receive anticipated QS-21 revenues would have a material adverse effect on our business, financial condition and results of operations.

Our patent on QS-21 composition of matter has already expired in virtually all territories and we rely on unpatented technology and know-how to protect our rights to QS-21.

Our patent on QS-21 composition of matter has already expired in virtually all territories, and our patent rights are limited to protecting certain combinations of QS-21 with other adjuvants or formulations of QS-21 with other agents. Although our licenses also rely on unpatented technology, know-how, and confidential information, these intellectual property rights may not be enforceable in certain jurisdictions and, therefore, we may not be able to collect anticipated revenue from our licensees. Any such inability would have a material adverse effect on our business, financial condition and results of operations.

Our HerpV therapeutic vaccine candidate is in early stage development and we may not be able to successfully develop this candidate.

Based on the results of our Phase 1 clinical trial of HerpV administered in combination with QS-21, we have advanced this product candidate into a Phase 2 trial that will measure the effect of vaccination on viral shedding in individuals infected with HSV-2 (genital herpes). This trial and further trials, and our HerpV development program in general, may not be successful or yield a partnering opportunity for us. While our Phase I clinical trial yielded positive immunological findings, it was limited in size and scope and the results may not translate into a clinical measurable effect on the frequency or duration of viral shedding in future trials with HerpV. In addition, even if our product candidate is successful in reducing viral shedding, it is possible that this could not translate into a clinical benefit. The success of the Phase 2 trial is also dependent on, upon other things, successful manufacture and release of the required investigational materials, enrolling sufficient patients and the adherence of these patients to the study protocol. Even if the trial is deemed successful, we may not have the resources required to advance the vaccine further and it is possible that research and discoveries by others will render our product candidate obsolete or noncompetitive.

Our licensee may not be able to successfully commercialize Oncophage in Russia and/or we may not receive any revenue from Oncophage sales or related efforts in Russia or certain other CIS countries.

In April 2008, the Russian Ministry of Public Health issued a registration certificate for the use of Prophage Series vaccine R-100 (Oncophage) for the treatment of kidney cancer patients at intermediate-risk for disease recurrence. The Russian registration was our first product approval from a regulatory authority.

Since approval, minimal sales have occurred in Russia. In December 2011, we secured a partner for Oncophage when we granted NewVac LLC (a subsidiary of ChemRar Ventures LLC, NewVac) an exclusive license to manufacture, market, and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. There is no guarantee that NewVac s efforts will be successful, or that we will receive any financial or other benefits from this arrangement. In addition, NewVac has the right to terminate its agreement with us at any time without cause.

While NewVac is establishing manufacturing capabilities in Russia, we are obligated to continue Oncophage manufacturing supply in our Lexington, MA, facility. As long as we manufacture Oncophage in the United States for

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importation into Russia, complexities unique to the logistics of this product may delay shipments and limit our ability to move commercial product in an efficient manner without incident. See Manufacturing problems may cause delays, unanticipated costs, or loss of revenue streams.

In addition, to date we have not been able to secure government reimbursement and there is no guarantee that NewVac will be able to do so. There appears to be a limited private-pay market in Russia, and many patients will not be capable of paying for Oncophage without third party reimbursement. The reimbursement system in Russia is uncertain and has experienced serious funding and administrative problems in its national and regional reimbursement programs. See If we, or our licensees, fail to obtain adequate levels of reimbursement for our product candidates there may be no commercially viable market for these products, or the commercial potential of these products may be significantly limited.

We may not be able to make vaccines from the Prophage Series available in countries other than Russia or in indications other than adjuvant renal cell carcinoma.

Oncophage is currently only approved for marketing in Russia for the adjuvant treatment of kidney cancer patients at intermediate-risk for disease recurrence and is the only product from our Prophage Series vaccines that is approved for marketing anywhere. The probability and timing of submissions and/or approval of Prophage Series vaccines in any other jurisdiction or indication is uncertain. A Phase 2 trial testing the Prophage Series vaccine candidate in newly diagnosed glioma has been fully enrolled and patient follow up is underway. Separately, a Phase 2 trial with G-200 in recurrent glioma has been completed and final data are in the process of being prepared for publication in a peer reviewed medical journal. These trials are not intended to provide the necessary evidence of efficacy and/or safety to support biologics license application (BLA) filings.

In 2008, we submitted a marketing authorization application (MAA), to the European Medicines Agency (EMA), requesting conditional authorization of Oncophage in earlier-stage, localized kidney cancer. After its review, the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a negative opinion on our MAA. Subsequently, we withdrew our application and we are no longer actively pursuing opportunities in this territory.

The U.S. Food and Drug Administration (FDA) has indicated that our Phase 3 clinical trials of Oncophage and Prophage Series vaccine M-200 cannot, by themselves, support BLA filings in the studies indications (renal cell carcinoma and metastatic melanoma). Furthermore, our existing data may not support registration or approval in other territories outside of Russia as this Phase 3 trial did not reach statistical significance in its primary endpoint of recurrence-free survival in the total patient population.

Due to our lack of resources, our ability to perform additional studies may be limited. In addition, studies may take years to complete and may fail to support regulatory filings for many reasons. Our Prophage Series vaccines are a novel class of patient-specific (derived from the patient s own tumor) oncology therapies, and the FDA and foreign regulatory agencies, including the EMA, which is responsible for product approvals in Europe, and Health Canada, which is responsible for product approvals in Canada, have limited experience in reviewing these types of therapies. Therefore, product candidates derived from the Prophage Series vaccines may experience high development costs and a long regulatory review process, either of which could delay or prevent commercialization efforts.

If we or our licensee are unable to purify heat shock proteins we may have difficulty successfully initiating or completing clinical trials or supporting commercial sales of Oncophage in Russia. Even if we or our licensees do successfully complete ongoing or future clinical trials or are successful manufacturing Oncophage commercially, we may have difficulty generating a sizable market or commercial sales.

Depending on the type and stage of cancer and the patient population, the ability to successfully develop and commercialize the Prophage Series vaccines for a particular cancer depends in part on our, and following successful technology transfer to our licensee, their ability to purify heat shock proteins from that type of cancer. If we or our licensee experience difficulties in purifying heat shock proteins for a sufficiently large number of patients in our clinical trials, we may face delays in enrolling sufficient patients and subsequently utilize more internal resources to satisfy enrolment requirements. Manufacturing failures may also lower the probability of a successful analysis of the data from clinical trials and, ultimately, the ability to obtain regulatory approvals. We have successfully manufactured product across many different cancer types, however, the success rate per indication has varied. We have evolved our manufacturing processes to better accommodate a wider range of tumor types. Our current manufacturing technologies have been successful in manufacturing product from approximately 92% of the RCC tumors received and approximately 85% of the tumors received from patients in our ongoing Phase 2 clinical trials in glioma. We expect to continue to devote resources to allow for a better evaluation of tumor characteristics and screening methods in an attempt to increase manufacturing success rates.

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In December 2011, we granted NewVac an exclusive license to manufacture, market, and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. To be successful, NewVac will have to build and equip a manufacturing facility, hire, train and retain staff, and validate the facility systems and process. There is no guarantee that NewVac will be able to accomplish these tasks and if they are unable or delayed in becoming operational, the commercial and developmental efforts may be delayed or limited. We may encounter problems with other types of cancer or patients as we expand our research. If we cannot overcome these problems, the number of patients or cancer types that our heat shock protein product candidates could treat would be limited. In addition, if we commercialize our heat shock protein product candidates, we may not be able to replicate past manufacturing success rates and we may face claims from patients for whom we are unable to produce a vaccine.

Risks associated with doing business internationally could negatively affect our business.

Oncophage is currently only approved for sale in Russia. Russia is an evolving market and regulatory, legal, and commercial structures are less predictable than in more mature markets. This unpredictability, as well as potential geopolitical instability in the Russian region, could negatively impact the regulatory and/or commercial environment there, which in turn could have an adverse effect on our business.

In addition, various other risks associated with foreign operations may impact our success. Possible risks include fluctuations in the value of foreign and domestic currencies, disruptions in the import, export, and transportation of patient tumors and our product, the product and service needs of foreign customers, difficulties in building and managing foreign relationships, the performance of our licensees or collaborators, and unexpected regulatory, economic, or political changes in foreign markets.

If we, or our licensees, fail to obtain adequate levels of reimbursement for our product candidates there may be no commercially viable market for these products, or the commercial potential of these products may be significantly limited.

Public and private insurance programs may determine that they will not cover our or our licensees product candidates. Government-sponsored health care systems typically pay a substantial share of health care costs, and they may regulate reimbursement levels of products to control costs. If we or our licensees are unsuccessful in obtaining substantial reimbursement for our product candidates from national or regional funds, we will have to rely on private-pay, which may delay or prevent our launch efforts, because the ability and willingness of patients to pay for our products is unclear.

We, or our licensees, may not be able to obtain health insurance coverage of our product candidates, and if coverage is obtained, it may be substantially delayed, or there may be significant restrictions on the circumstances in which the products would be reimbursed. We are unable to predict what impact any future regulation or third-party payer initiatives relating to reimbursement will have on our sales.

Our competitors in the biotechnology and pharmaceutical industries may have superior products, manufacturing capability, selling and marketing expertise and/or financial and other resources.

Our product candidates and the product candidates in development by our collaborative partners may fail because of competition from major pharmaceutical companies and specialized biotechnology companies that market products, or that are engaged in the development of product candidates, directed at cancer, infectious diseases and degenerative disorders.

Genentech markets Avastin and Eisai markets Gliadel, both for treatment of recurrent glioma. In addition, TVAX Biomedical and Stemline Therapeutics are developing immunotherapy candidates (TVI-Brain-1 and SL-701, respectively) for recurrent glioma. Schering Corporation, a subsidiary of Merck, markets Temodar for treatment of patients with newly diagnosed glioma. Other companies are developing vaccine candidates for the treatment of patients with newly diagnosed glioma, such as Innocell Corp (Immuncell-LC), ImmunoCellular Therapeutics (ICT-107), Northwest Biotherapeutics (DC-Vax), Immatics (IMA-950), Activartis Biotech (GBM-Vax) and Celldex (CDX-110). Celldex is also currently developing a vaccine candidate for recurrent glioma. Other companies may begin such development as well.

There is no guarantee that our products or product candidates will be able to compete with potential future products being developed by our competitors. For example, Oncophage may compete with therapies currently in development for non-metastatic renal cell carcinoma, such as sorafenib, sunitinib, temsirolimus, bevacizumab and pazopanib. As vaccines from our Prophage Series are potentially developed in other indications, they could face additional competition in those indications. In addition, and prior to regulatory approval, our Prophage Series vaccines and all of our other product candidates may compete for access to patients with other products in clinical development, with products approved for use in the indications we are studying, or with off-label use of products in the indications we are studying. We anticipate that we will face increased competition in the future as new companies enter markets we seek to address and scientific developments surrounding immunotherapy and other traditional cancer therapies continue to accelerate.

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Valtrex (GSK) and Famvir (Novartis) are small molecule drugs marketed for treatment of genital herpes. Other companies are engaged in research for vaccines for treatment of genital herpes including Genocea and Vical. AiCuris Gmbh is engaged in clinical research of a small molecule drug for treatment of genital herpes and has completed a Phase 2 trial.

Our patent to purified QS-21 expired in most territories in 2008. Additional protection for our QS-21 proprietary adjuvant in combination with other agents is provided by our other patents. Our license and manufacturing agreements for QS-21 generally provide royalties independent of patent expiry for at least 10 years after commercial launch, with some exception. However, there is no guarantee that we will be able to collect royalties in the future.

We are aware of compounds that claim to be identical to QS-21 that are being used in clinical trials. Several other vaccine adjuvants are in development and could compete with QS-21 for inclusion in vaccines in development. These adjuvants include, but are not limited to, oligonucleotides, under development by Pfizer, Idera, Colby, and Dynavax, MF59 under development by Novartis, IC31, under development by Intercell, and MPL, under development by GSK. In the past, the Company has provided QS-21 to other entities under materials transfer arrangements. In at least one instance, it is possible that this material was used unlawfully to develop synthetic formulations and/or derivatives of QS-21. Companies such as Adjuvance Technologies, Inc. and CSL Limited, as well as academic institutions and manufacturers of saponin extracts, are developing saponin adjuvants, including derivatives and synthetic formulations. These sources may be competitive with our ability to do future partnering and licensing deals with QS-21.

Many of our competitors, including large pharmaceutical companies, have greater financial and human resources and more experience than we do. Our competitors may:

- commercialize their product candidates sooner than we commercialize our own;
- develop safer or more effective therapeutic drugs or preventive vaccines and other therapeutic products;
- implement more effective approaches to sales and marketing and capture some of our potential market share;
- establish superior intellectual property positions;
- discover technologies that may result in medical insights or breakthroughs, which render our drugs or vaccines obsolete, possibly before they generate any revenue; or
- adversely affect our ability to recruit patients for our clinical trials.

Manufacturing problems may cause delays, unanticipated costs, or loss of revenue streams.

If the future commercial demand for Oncophage or clinical demand for other product candidates is substantially greater than we anticipate, our capacity may not be able to meet product demand. In addition, higher manufacturing loads may result in higher manufacturing failure rates as the operation becomes more complex. We currently manufacture our Prophage Series vaccines in our Lexington, MA facility. While we believe we will be able to cover demand in the near term, there is no guarantee that we will be able to meet all future or unanticipated increases in demand, and a failure to do so could adversely affect our business. Such demand may also limit our ability to manufacture product in support of clinical trials, and this could cause a delay or failure in our Prophage Series vaccine development programs. Manufacturing of Prophage Series vaccines is complex, and various factors could cause delays or an inability to supply vaccine. Deviations in the processes controlling manufacture could result in production failures. Furthermore, we have limited manufacturing resources and there is no assurance that we will be able to obtain the necessary resources, timely or at all, to meet any increased demand.

Regulatory bodies may require us to make our manufacturing facility a single product facility. In such an instance, we would no longer have the ability to manufacture products other than Prophage Series vaccines in our current facility.

Except in the case of GSK and JANSSEN AI, we have retained worldwide manufacturing rights for QS-21. We have the right to subcontract manufacturing for QS-21 for our other existing and future QS-21 manufacturing and supply needs, and we have a supply agreement with a contract manufacturer for the production of QS-21 through September 2014. If we are not able to renew this agreement we may not be able to supply QS-21 to meet future supply obligations on favorable terms or at all. For example, although GSK is a source of QS-21 supply for us, their obligation to supply is for a limited duration, and various factors could impact our decision to exercise this right. In addition, we or our currently contracted suppliers may not have the ability to manufacture commercial grade QS-21.

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We currently rely upon and expect to continue to rely upon third parties, potentially including our collaborators or licensees, to produce materials required to support our product candidates, preclinical studies, clinical trials, and commercial efforts. A number of factors could cause production interruptions at our manufacturing facility or at our contract manufacturers or suppliers, including equipment malfunctions, labor or employment retention problems, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers. Alternatively, there is the possibility we may have excess manufacturing capacity if product candidates do not progress as planned.

There are a limited number of contract manufacturers or suppliers that are capable of manufacturing our product candidates or the materials used in their manufacture. If we are unable to do so ourselves or to arrange for third-party manufacturing or supply of these product candidates or materials, or to do so on commercially reasonable terms, we may not be able to complete development of these product candidates or commercialize them ourselves or through our collaborative partners or licensees. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

Manufacturing is also subject to extensive government regulation. Regulatory authorities must approve the facilities in which human health care products are produced. In addition, facilities are subject to ongoing inspections, and minor changes in manufacturing processes may require additional regulatory approvals, either of which could cause us to incur significant additional costs and lose revenue.

The drug development and approval process is uncertain, time-consuming, and expensive.

Clinical development, including preclinical testing and the process of obtaining and maintaining regulatory approvals for new therapeutic products, is lengthy, expensive, and uncertain. As of September 30, 2012, we have spent approximately 18 years and $296.4 million on our research and development program in heat shock proteins for cancer. It also can vary substantially based on the type, complexity, and novelty of the product. We must provide regulatory authorities with manufacturing, product characterization, and preclinical and clinical data demonstrating that our product candidates are safe and effective before they can be approved for commercial sale. It may take us many years to complete our testing, and failure can occur at any stage of testing. Interim results of preclinical studies or clinical trials do not necessarily predict their final results, and acceptable results in early studies might not be seen in later studies. Any preclinical or clinical test may fail to produce results satisfactory to regulatory authorities for many reasons, including but not limited to insufficient product characterization, poor study structure conduct or statistical analysis planning, failure to enroll a sufficient number of patients or failure to prospectively identify the most appropriate patient eligibility criteria, and collectability of data. Preclinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, adverse medical events during a clinical trial, or safety issues resulting from products of the same class of drug could require a preclinical study or clinical trial to be repeated or cause a program to be terminated, even if other studies or trials relating to the program are successful. We or the FDA, other regulatory agencies, or an institutional review board may suspend or terminate human clinical trials at any time on various grounds.

The timing and success of a clinical trial is dependent on obtaining and maintaining sufficient cash resources, successful production of clinical trial material, enrolling sufficient patients in a timely manner, avoiding serious or significant adverse patient reactions, and demonstrating efficacy of the product candidate in order to support a favorable risk versus benefit profile, among other considerations. The timing and success of our clinical trials, in particular, are also dependent on clinical sites and regulatory authorities accepting each trial s protocol, statistical analysis plan, product characterization tests, and clinical data. In addition, regulatory authorities may request additional information or data that is not readily available. Delays in our ability to respond to such requests would delay, and failure to adequately address concerns would prevent, our commercialization efforts. We have encountered in the past, and may encounter in the future, delays in initiating trial sites and enrolling patients into our clinical trials. Future enrollment delays will postpone the dates by which we expect to complete the impacted trials and the potential receipt of regulatory approval. There is no guarantee we will successfully initiate and/or complete our clinical trials.

Delays or difficulties in obtaining regulatory approvals or clearances for our product candidates may:

- adversely affect the marketing of any products we or our licensees or collaborators develop;
- impose significant additional costs on us or our licensees or collaborators;

diminish any competitive advantages that we or our licensees or collaborators may attain;

limit our ability to receive royalties and generate revenue and profits; and

adversely affect our business prospects and ability to obtain financing.

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Delays or failures in our receiving regulatory approval for our product candidates in a timely manner may result in us having to incur additional development expense and subject us to having to secure additional financing. As a result, we may not be able to commercialize them in the timeframe anticipated, and our business will suffer.

Even if we receive marketing approval for our product candidates, such product approvals could be subject to restrictions or withdrawals. Regulatory requirements are subject to change.

Regulatory authorities generally approve products for particular indications. If an approval is for a limited indication, this limitation reduces the size of the potential market for that product. Product approvals, once granted, are subject to continual review and periodic inspections by regulatory authorities. Our operations and practices are subject to regulation and scrutiny by the United States government, as well as governments of any other countries in which we do business or conduct activities. Later discovery of previously unknown problems or safety issues, and/or failure to comply with domestic or foreign laws, knowingly or unknowingly, can result in various adverse consequences, including, among other things, possible delay in approval or refusal to approve a product, warning letters, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to renew marketing applications, complete withdrawal of a marketing application, and/or criminal prosecution, withdrawal of an approved product from the market, and/or exclusion from government health care programs. Such regulatory enforcement could have a direct and negative impact on the product for which approval is granted, but also could have a negative impact on the approval of any pending applications for marketing approval of new drugs or supplements to approved applications.

Because we are a company operating in a highly regulated industry, regulatory authorities could take enforcement action against us in connection with our, or our licensees or collaborators, business and marketing activities for various reasons. For example, the United States Foreign Corrupt Practices Act prohibits U.S. companies and their representatives from offering, promising, authorizing, or making payments to foreign officials for the purpose of obtaining or retaining business abroad.

From time to time, new legislation is passed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA and other foreign health authorities. Additionally, regulations and guidance are often revised or reinterpreted by health agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted, or whether regulations, guidance, or interpretations will change, and what the impact of such changes, if any, may be.

New data from our research and development activities, and/or resource considerations could modify our strategy and result in the need to adjust our projections of timelines and costs of programs.

Because we are focused on novel technologies, our research and development activities, including our nonclinical studies and clinical trials, involve the ongoing discovery of new facts and the generation of new data, based on which we determine next steps for a relevant program. These developments can occur with varying frequency and constitute the basis on which our business is conducted. We need to make determinations on an ongoing basis as to which of these facts or data will influence timelines and costs of programs. We may not always be able to make such judgments accurately, which may increase the costs we incur attempting to commercialize our product candidates. We monitor the likelihood of success of our initiatives and we may need to discontinue funding of such activities if they do not prove to be commercially feasible, due to our limited resources.

We may need to successfully address a number of technological challenges in order to complete development of our product candidates. Moreover, these product candidates may not be effective in treating any disease or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude our obtaining regulatory approvals or prevent or limit commercial use.

Failure to enter into significant licensing, distribution and/or collaboration agreements may hinder our efforts to develop and commercialize our product candidates and will increase our need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations.

We have been engaged in efforts to enter into licensing, distribution and/or collaborative agreements with one or more pharmaceutical or biotechnology companies to assist us with development and/or commercialization of our product candidates. If we are successful in entering into such agreements, we may not be able to negotiate agreements with economic terms similar to those negotiated by other companies. We may not, for example, obtain significant upfront payments, substantial royalty rates or milestones. If we fail to enter into any such agreements, our efforts to develop and/or commercialize our products or product candidates may be undermined. In addition, if we do not raise funds through any

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such agreements, we will need to rely on other financing mechanisms, such as sales of debt or equity securities, to fund our operations. Such financing mechanisms, if available, may not be sufficient or timely enough to advance our programs forward in a meaningful way in the short-term.

While we have been pursuing these business development efforts for several years, we have not entered into a substantial agreement relating to the potential development or commercialization of Oncophage or any of the other Prophage Series vaccines other than the recent agreement with NewVac giving them an exclusive license to manufacture, market and sell Oncophage as well as pursue a development program in the Russian Federation and certain other CIS countries. Due to the announcements in March 2006 that part I of our Phase 3 trial in renal cell carcinoma did not achieve its primary endpoint in the intent to treat population, and in November 2009, that the CHMP adopted a negative opinion on our MAA, and because companies may be skeptical regarding the potential success of a patient-specific product candidate, many other companies have been and may continue to be unwilling to commit to an agreement prior to receipt of additional clinical data, if at all.

In addition, we would consider license and/or co-development opportunities to advance HerpV. This product is at an early stage and collaborative partners or licensees may defer discussions until results from our Phase 2 clinical trial become available, or they may not engage in such discussions at all.

Because we rely on collaborators and licensees for the development and commercialization of most of our product candidate programs, these programs may not prove successful, and/or we may not receive significant payments from such parties.

Part of our strategy is to develop and commercialize a majority of our product candidates by continuing or entering into arrangements with academic, government, or corporate collaborators and licensees. Our success depends on our ability to negotiate such agreements and on the success of the other parties in performing research, preclinical and clinical testing, completing regulatory applications, and commercializing product candidates. For example, the development of candidates from the Prophage G Series is currently dependent in large part on the efforts of our institutional collaborators, such as the Brain Tumor Research Center at the University of California, San Francisco, which is conducting Phase 2 clinical trials of Prophage Series vaccines G-100 and G-200 for the treatment of glioma. In addition, substantially all product candidates containing QS-21, other than HerpV, depend on the success of our collaborative partners or licensees, and the Company s relationships with these third parties. Such product candidates depend on our collaborators and licensees successfully enrolling patients and completing clinical trials, being committed to dedicating the resources to advance these product candidates, obtaining regulatory approvals, and successfully commercializing product candidates. In addition, when our licensees or third party collaborators sponsor clinical trials using our product candidates, we cannot control the timing or quality of such trials or related activities.

Development activities may fail to produce marketable products due to unsuccessful results or abandonment of these programs, failure to enter into future collaborations or license agreements, or the inability to manufacture product supply requirements for our collaborators and licensees. Several of our agreements also require us to transfer important rights and regulatory compliance responsibilities to our collaborators and licensees. As a result of these collaborative agreements, we will not control the nature, timing, or cost of bringing these product candidates to market. Our collaborators and licensees could choose not to devote resources to these arrangements or, under certain circumstances, may terminate these arrangements early. They may cease pursuing product candidates or elect to collaborate with different companies. In addition, these collaborators and licensees, outside of their arrangements with us, may develop technologies or products that are competitive with those that we are developing. From time to time, we may also become involved in disputes with our collaborators or licensees. Such disputes could result in the incurrence of significant expense, or the termination of collaborations. We may be unable to fulfill all of our obligations to our collaborators, which may result in the termination of collaborations. As a result of these factors, our strategic collaborations may not yield revenue. Furthermore, we may be unable to enter into new collaborations or enter into new collaborations on favorable terms. Failure to generate significant revenue from collaborations would increase our need to fund our operations through sales of debt or equity securities and would negatively affect our business prospects.

If we fail to sustain and further build our intellectual property rights, competitors may be able to take advantage of our research and development efforts to develop competing products.

If we are not able to protect our proprietary technology, trade secrets, and know-how, our competitors may use our past developments and technologies to develop competing products. As of February 2012, we had exclusive rights to 74 issued United States patents and 114 issued foreign patents. As of February 2012, we also had exclusive rights to six pending United States patent applications and 24 pending foreign patent applications. However, our patents may not protect us against our competitors. Our patent positions, and those of other pharmaceutical and biotechnology companies, are generally uncertain and involve complex legal, scientific, and factual questions. The standards which the United States

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Patent and Trademark Office uses to grant patents, and the standards which courts use to interpret patents, are not always applied predictably or uniformly and can change, particularly as new technologies develop. Consequently, the level of protection, if any, that will be provided by our patents if we attempt to enforce them, and they are challenged, is uncertain. In addition, the type and extent of patent claims that will be issued to us in the future is uncertain. Any patents that are issued may not contain claims that permit us to stop competitors from using similar technology.

Furthermore, the product development timeline for biotechnology products is lengthy and it is possible that our issued patents covering our product candidates in the United States and other jurisdictions may expire prior to commercial launch. In addition, because our patent on QS-21 composition of matter has already expired in virtually all territories, our patent rights are limited to protecting certain combinations of QS-21 with other adjuvants or formulations of QS-21 with other agents, e.g., excipients that improve performance of the compound. However, there is no guarantee that a third party would necessarily choose to use QS-21 in combination with such adjuvants or formulate it with the excipients covered by our patents. We are aware of at least one other party that makes a synthetic version of QS-21, claimed by such party to be equivalent in activity to natural QS-21, and has also developed derivatives of QS-21, which have shown biological activity.

In addition to our patented technology, we also rely on unpatented technology, trade secrets, and confidential information. We may not be able to effectively protect our rights to this technology or information. Other parties may independently develop substantially equivalent information and techniques or otherwise gain access to or disclose our technology. We generally require each of our employees, consultants, collaborators, and certain contractors to execute a confidentiality agreement at the commencement of an employment, consulting, collaborative, or contractual relationship with us. However, these agreements may not provide effective protection of our technology or information, or in the event of unauthorized use or disclosure, they may not provide adequate remedies.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights in, or to use, our technology.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. We may become a party to patent litigation or other proceedings regarding intellectual property rights.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask a court to rule that our patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of our patents. In addition, there is a risk that the court will decide that our patents are not valid and that we do not have the right to stop the other party from using the claimed inventions. There is also the risk that, even if the validity of our patents is upheld, the court will refuse to stop the other party on the grounds that such other party s activities do not infringe our patents.

We may not have rights under some patents or patent applications related to some of our existing and proposed products or processes. Third parties may own or control these patents and patent applications in the United States and abroad. Therefore, in some cases, such as those described below, in order to develop, use, manufacture, sell, or import some of our existing or proposed products, or develop or use some of our existing or proposed processes, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad, or those that might issue from United States and foreign patent applications. In such an event, we likely would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to exploit these products or processes.

Furthermore, a third party may claim that we are using inventions covered by such third-party s patents or other intellectual property rights and may go to court to stop us from engaging in our normal operations and activities. These lawsuits are expensive. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. There is a risk that a court would decide that we are infringing the third-party s patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party substantial damages for having violated the other party s patents. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Moreover, patent holders sometimes send communications to a number of companies in related fields suggesting possible infringement, and we, like a number of biotechnology companies, have received such communications in the past and may receive others in the future. If we are sued for patent infringement, we would need to demonstrate that our products either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, which we may not be able to do. Proving invalidity, in particular, is difficult, since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

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If patent litigation or other proceeding is resolved against us, we or our licensees or collaborators may be enjoined from using, manufacturing, selling, or importing our products or processes without a license from the other party, and we may be held liable for significant damages. We may not be able to obtain any required licenses on commercially acceptable terms or at all.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to enter into collaborations with other entities, obtain financing, or compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time and other resources.

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to various license agreements under which we receive the right to practice and use important third-party patent rights and we may enter into additional licenses in the future. Our existing licenses impose, and we expect future licenses will impose, various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, the licensor may have the right to terminate the license, in which event we might not be able to market any product that is covered by the licensed patents.

We have limited internal resources and if we fail to recruit and/or retain the services of key employees and external consultants as needed, we may not be able to achieve our strategic and operational objectives.

Garo H. Armen, Ph.D., the Chairman of our Board of Directors and our Chief Executive Officer, co-founded the Company in 1994, and has been, and continues to be, integral to building our company and developing our technology. If Dr. Armen severed his relationship with Agenus, our business may be adversely impacted.

Effective December 1, 2005, we entered into an employment agreement with Dr. Armen. Subject to the earlier termination as provided in the agreement, the agreement had an original term of one year and is automatically extended thereafter for successive terms of one year each, unless either party provides notice to the other at least ninety days prior to the expiration of the original or any extension term. Dr. Armen plays an important role in our day-to-day activities. We do not carry key employee insurance policies for Dr. Armen or any other employee.

We also rely on a small staff of highly trained and experienced senior management and scientific, administrative and operations personnel and consultants to conduct our business. Reductions in our staffing levels have eliminated redundancies in key capabilities and skill sets among our full time staff and required us to rely more heavily on outside consultants and third parties. In addition, if in the future we need to perform sales, marketing and distribution functions for commercial and/or international operations, we will need to recruit experienced personnel and/or engage external consultants incurring significant expenditures.

Reduction in expenses and resulting changes to our compensation and benefit programs have reduced the competitiveness of these programs and thereby increased employee retention risk. The competition for qualified personnel in the biotechnology field is intense, and if we are not able to continue to attract and retain qualified personnel and/or maintain positive relationships with our outside consultants, we may not be able to achieve our strategic and operational objectives.

We may face litigation that could result in substantial damages and may divert management s time and attention from our business.

We may currently be a party, or may become a party, to legal proceedings, claims and investigations that arise in the ordinary course of business such as, but not limited to, patent, employment, commercial and environmental matters. While we currently believe that the ultimate outcome of any of these proceedings will not have a material adverse effect on our financial position, results of operations, or liquidity, litigation is subject to inherent uncertainty. Furthermore, litigation consumes both cash and management attention.

We maintain property and general commercial insurance coverage as well as errors and omissions and directors and officers insurance policies. This insurance coverage may not be sufficient to cover us for future claims.

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Product liability and other claims against us may reduce demand for our products and/or result in substantial damages.

We face an inherent risk of product liability exposure related to testing our product candidates in human clinical trials and commercial sales of Oncophage in Russia, and may face even greater risks if we sell Oncophage in other territories and/or sell our other product candidates commercially. An individual may bring a product liability claim against us if Oncophage or one of our product candidates causes, or merely appears to have caused, an injury. Product liability claims may result in:

decreased demand for Oncophage or our product candidates;

regulatory investigations;

injury to our reputation;

withdrawal of clinical trial volunteers;

costs of related litigation; and

substantial monetary awards to plaintiffs.

We manufacture the Prophage Series vaccines from a patient s cancer cells, and medical professionals must inject the vaccines into the same patient from which they were manufactured. A patient may sue us if a hospital, a shipping company, or we fail to receive the removed cancer tissue or deliver that patient s vaccine. We anticipate that the logistics of shipping will become more complex if the number of patients we treat increases and that shipments of tumor and/or vaccines may be lost, delayed, or damaged. Additionally, complexities unique to the logistics of commercial products may delay shipments and limit our ability to move commercial product in an efficient manner without incident. To date, we have obtained transportation insurance coverage for commercial Oncophage being shipped to Russia. We do not have any other insurance that covers loss of or damage to the Prophage Series vaccines or tumor material, and we do not know whether such insurance will be available to us at a reasonable price or at all. We have limited product liability coverage for use of our product candidates. Our product liability policy provides $10.0 million aggregate coverage and $10.0 million per occurrence coverage. This limited insurance coverage may be insufficient to fully cover us for future claims.

If we do not comply with environmental laws and regulations, we may incur significant costs and potential disruption to our business.

We use or may use hazardous, infectious, and radioactive materials, and recombinant DNA in our operations, which have the potential of being harmful to human health and safety or the environment. We store these hazardous (flammable, corrosive, toxic), infectious, and radioactive materials, and various wastes resulting from their use, at our facilities pending use and ultimate disposal. We are subject to a variety of federal, state, and local laws and regulations governing use, generation, storage, handling, and disposal of these materials. We may incur significant costs complying with both current and future environmental health and safety laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, the Environmental Protection Agency, the Drug Enforcement Agency, the Department of Transportation, the Centers for Disease Control and Prevention, the National Institutes of Health, the International Air Transportation Association, and various state and local agencies. At any time, one or more of the aforementioned agencies could adopt regulations that may affect our operations. We are also subject to regulation under the Toxic Substances Control Act and the Resource Conservation Development programs.

Although we believe that our current procedures and programs for handling, storage, and disposal of these materials comply with federal, state, and local laws and regulations, we cannot eliminate the risk of accidents involving contamination from these materials. Although we have a workers compensation liability policy, we could be held liable for resulting damages in the event of an accident or accidental release, and such damages could be substantially in excess of any available insurance coverage and could substantially disrupt our business.

Risks Related to our Common Stock

Unaffiliated holders of certain convertible securities may convert such securities into a substantial percentage of our outstanding common stock.

According to publicly filed documents, Mr. Brad M. Kelley beneficially owns approximately 924,000 shares of our outstanding common stock and 31,620 shares of our series A convertible preferred stock. The shares of preferred stock are currently convertible at any time into approximately 333,000 shares of common stock at an initial conversion price of $94.86, are non-voting, and carry a 2.5% annual dividend yield. If Mr. Kelley had converted all of the shares of preferred stock on September 30, 2012, he would have held approximately 5% of our outstanding common stock. We currently have a right of first refusal agreement with Mr. Kelley that provides us with limited rights to purchase certain of Mr. Kelley s shares if he proposes to sell them to a third party.

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Ingalls & Snyder LLC holds $31.2 million aggregate principal amount of our 2006 Notes. Upon maturity in 2014, we may elect to repay the outstanding balance of our 2006 Notes in cash or in common stock, subject to certain limitations. If we elect to satisfy the outstanding balance with common stock at maturity (August 2014), the number of shares issued will be determined by dividing the cash obligation by 90 percent of the weighted average price of the common shares for the 20 trading days preceding the maturity date of the 2006 Notes. This right is subject to our market capitalization exceeding $300 million at such time. In no event will the note holder be obligated to accept equity that would result in them owning in excess of 9.99% of the Company s outstanding common stock at any given time in connection with any conversion, redemption, or repayment of the 2006 Notes.

Collectively, Mr. Kelley and Dr. Armen, our Chief Executive Officer, control approximately 10% of our outstanding common stock as of September 30, 2012, providing the ability, if they vote in the same manner, to determine the outcome of matters submitted to a stockholder vote. If Mr. Kelley were to convert all of his preferred stock into common stock, the combined total would increase to 11%. Additional purchases of our common stock by Mr. Kelley also would increase both his percentage of outstanding voting rights and the percentage combined with our Chief Executive Officer. While Mr. Kelley s shares of preferred stock do not carry voting rights, the shares of common stock issuable upon conversion carry the same voting rights as other shares of common stock.

Our stock may be delisted from The Nasdaq Capital Market, which could affect its market price and liquidity.

Our common stock is currently listed on The Nasdaq Capital Market (Nasdaq) under the symbol AGEN. In the event that we fail to maintain compliance with the applicable listing requirements, our common stock could become subject to delisting from Nasdaq. Although we are currently in compliance with all of the listing standards for listing on Nasdaq, we cannot provide any assurance that we will continue to be in compliance in the future. We have been non-compliant with the minimum bid price requirement set forth in Nasdaq Marketplace Rule 5550(a)(2) three times since our move to The Nasdaq Capital Market in April 2009.

Provisions in our organizational documents could prevent or frustrate attempts by stockholders to replace our current management.

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us without the consent of our Board of Directors. Our certificate of incorporation provides for a staggered board and removal of directors only for cause. Accordingly, stockholders may elect only a minority of our Board at any annual meeting, which may have the effect of delaying or preventing changes in management. In addition, under our certificate of incorporation, our Board of Directors may issue additional shares of preferred stock and determine the terms of those shares of stock without any further action by our stockholders. Our issuance of additional preferred stock could make it more difficult for a third party to acquire a majority of our outstanding voting stock and thereby effect a change in the composition of our Board of Directors. Our certificate of incorporation also provides that our stockholders may not take action by written consent. Our bylaws require advance notice of stockholder proposals and director nominations and permit only our president or a majority of the Board of Directors to call a special stockholder meeting. These provisions may have the effect of preventing or hindering attempts by our stockholders to replace our current management. In addition, Delaware law prohibits a corporation from engaging in a business combination with any holder of 15% or more of its capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our Board of Directors may use this provision to prevent changes in our management. Also, under applicable Delaware law, our Board of Directors may adopt additional anti-takeover measures in the future.

The first right to negotiate provision contained in our agreement with one of our licensees could hinder or delay a change of control of the Company or the sale of certain of our assets

We have entered into a First Right to Negotiate and Amendment Agreement with GSK that affords GSK, one of our licensees, a first right to negotiate with us in the event we determine to initiate a process to effect a change of control of our company with, or to sell certain of our assets to, an unaffiliated third party or in the event that a third party commences an unsolicited tender offer seeking a change of control of our company. In such event, we must provide GSK a period of time to determine whether it wishes to negotiate the terms of such a transaction with us. If GSK affirmatively so elects, we are required to negotiate with GSK in good faith towards effecting a transaction of that nature for a specified period. During the negotiation period, we are obligated not to enter into a definitive agreement with a third party that would preclude us from negotiating and/or executing a definitive agreement with GSK. If GSK determines not to negotiate with us or we are unable to come to an agreement with GSK during this period, we may enter into the specified change of control or sale transaction

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within the ensuing 12 months, provided that such a transaction is not on terms in the aggregate that are materially less favorable to us and our stockholders (as determined by our Board of Directors, in its reasonable discretion) than terms last offered to us by GSK in a binding written proposal during the negotiation period. The first right to negotiate terminates on March 2, 2017. Although GSK s first right to negotiate does not compel us to enter into a transaction with GSK nor prevent us from negotiating with or entering into a transaction with a third party, the first right to negotiate could inhibit a third party from engaging in discussions with us concerning such a transaction or delay our ability to effect such a transaction with a third party.

Our stock has historically had low trading volume, and its public trading price has been volatile.

Between our initial public offering on February 4, 2000 and September 30, 2012, and for the nine months ended September 30, 2012, the closing price of our common stock has fluctuated between $1.80 and $315.78 per share and $2.10 and $7.04 per share, respectively. The average daily trading volume for the nine months ended September 30, 2012 was approximately 208,000 shares. The market may experience significant price and volume fluctuations that are often unrelated to the operating performance of individual companies. In addition to general market volatility, many factors may have a significant adverse effect on the market price of our stock, including:

- continuing operating losses, which we expect over the next several years as we continue our development activities;
- announcements of decisions made by public officials;
- results of our preclinical studies and clinical trials;
- announcements of new collaboration agreements with strategic partners or developments by our existing collaborative partners;
- announcements of technological innovations, new commercial products, failures of products, or progress toward commercialization by our competitors or peers;
- developments concerning proprietary rights, including patent and litigation matters;
- publicity regarding actual or potential results with respect to product candidates under development; and
- quarterly fluctuations in our financial results.

The sale of a significant number of shares could cause the market price of our stock to decline.

The sale by us or the resale by stockholders of a significant number of shares of our common stock could cause the market price of our common stock to decline. As of September 30, 2012, we had approximately 24,585,000 shares of common stock outstanding. All of these shares are eligible for sale on Nasdaq, although certain of the shares are subject to sales volume and other limitations. We have filed registration statements to permit the sale of approximately 6,200,000 shares of common stock under our equity incentive plans. We have also filed registration statements to permit the sale of approximately 167,000 shares of common stock under our employee stock purchase plan, to permit the sale of 225,000 shares of common stock under our Directors Deferred Compensation Plan (DDCP), to permit the sale of approximately 8,274,000 shares of common stock pursuant to various private placement agreements and to permit the sale of approximately 5,000,000 shares of our common stock pursuant to our At Market Issuance Sales Agreement. As of September 30, 2012, an aggregate of 9.9 million of these shares remain available for sale. The market price of our common stock may decrease based on the expectation of such sales.

As of September 30, 2012, options to purchase 2,769,311 shares of our common stock with a weighted average exercise price per share of $7.09 were outstanding. These options are subject to vesting that occurs over a period of up to four years following the date of grant. As of

September 30, 2012, we have 257,415 nonvested shares outstanding.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 and to comply with changing regulation of corporate governance and public disclosure could have a material adverse effect on our operating results and the price of our common stock.

The Sarbanes-Oxley Act of 2002 and rules adopted by the Securities and Exchange Commission and Nasdaq have resulted in significant costs to us. In particular, our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002 and related regulations regarding the required assessment of our internal control over financial reporting, and our independent registered public accounting firm s audit of internal control over financial reporting, have required commitments of significant management time. We expect these commitments to continue.

Our internal control over financial reporting (as defined in Rules 13a-15 of the Exchange Act) is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated

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financial statements for external purposes in accordance with U.S. GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect all deficiencies or weaknesses in our financial reporting. While our management has concluded that there were no material weaknesses in our internal control over financial reporting as of December 31, 2011, our procedures are subject to the risk that our controls may become inadequate because of changes in conditions or as a result of a deterioration in compliance with such procedures. No assurance is given that our procedures and processes for detecting weaknesses in our internal control over financial reporting will be effective.

Changing laws, regulations and standards relating to corporate governance and public disclosure, are creating uncertainty for companies. Laws, regulations and standards are subject to varying interpretations in some cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided, which could result in continuing uncertainty regarding compliance matters and higher costs caused by ongoing revisions to disclosure and governance practices. If we fail to comply with these laws, regulations and standards, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the Securities Exchange Commission. Any such action could adversely affect our operating results and the market price of our common stock.

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Item 6. ***Exhibits***

The Exhibits listed in the Exhibit Index are included in this Quarterly Report on Form 10-Q.

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AGENUS INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 7, 2012

AGENUS INC.

/s/ CHRISTINE M. KLASKIN
Christine M. Klaskin
VP, Finance, Principal Financial Officer, Principal

Accounting Officer

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Exhibit Index

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 10, 2002 and incorporated herein by reference.
3.1.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Antigenics Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on June 11, 2007 and incorporated herein by reference.
3.1.2	Certificate of Ownership and Merger changing the name of the corporation to Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference.
3.1.3	Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 30, 2011 and incorporated herein by reference.
3.1.4	Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation of Agenus Inc. Filed as Exhibit 3.1.4 to our Quarterly Report on Form 10-Q (File No. 0-29089) for the quarter ended June 30, 2012 and incorporated herein by reference.
3.2	Fifth Amended and Restated By-laws of Agenus Inc. Filed as Exhibit 3.2 to our Current Report on Form 8-K (File No. 0-29089) filed on January 6, 2011 and incorporated herein by reference.
3.3	Certificate of Designation, Preferences and Rights of the Series A Convertible Preferred Stock of Agenus Inc. filed with the Secretary of State of the State of Delaware on September 24, 2003. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 25, 2003 and incorporated herein by reference.
3.4	Certificate of Designations, Preferences and Rights of the Class B Convertible Preferred Stock of Agenus Inc. Filed as Exhibit 3.1 to our Current Report on Form 8-K (File No. 0-29089) filed on September 5, 2007 and incorporated herein by reference.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended. Filed herewith.
32.1(1)	Certification of Chief Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Submitted herewith.
101.INS	XBRL Instance Document(2)
101.SCH	XBRL Taxonomy Extension Schema Document(2)
101.CAL	XBRL Calculation Linkbase Document(2)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document(2)
101.LAB	XBRL Label Linkbase Document(2)
101.PRE	XBRL Taxonomy Presentation Linkbase Document(2)

(1) This certification accompanies the Quarterly Report on Form 10-Q and is not filed as part of it.

(2) XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.